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Applicants : Reinhard Koch, Frank Müller and Jorgen Friies
Serial No. : 09/308,407
Filed : July 8, 1999
Title : SEALING MEDIUM FOR COMPOSITE PACKAGING MATERIALS
Group : 1772
Examiner : Michael Miggins
Attorney Dkt No. : RO0230US (#90568)

C. P. ROSENTHAL

Box AF
Commissioner for Patents
Washington, D.C. 20231

AMENDED APPEAL BRIEF

Dear Sir:

This amended brief is submitted, in triplicate, in response to the Notice of Non-Compliance with 37 CFR 1.192(c) dated July 25, 2001. It is submitted with a Petition for Revival of an Application for Patent Abandoned Unintentionally under 37 CFR 1.137(b) (PTO/SB/64), a Credit Card Payment Form (PTO-2038)- and a Transmittal Form (PTO/SB/21).

Real Party in Interest The real party in interest is the assignee of the applicants, LTS Lohmann Therapie-Systeme AG. This application was assigned from Reinhard Koch, Frank Müller and Jorgen Friies to LTS Lohmann Therapie-Systeme AG on May 28, 1999 and recorded in the United States Patent and Trademark Office on July 8, 1999 at Reel 010131 and Frame 0870 on four (4) pages. A copy of the assignment document was submitted with the original Appeal Brief on May 14, 2001.

Related Appeals and Interferences There are no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims Claims 9-17 are pending in the application. The rejection of claims 9-17 is being appealed.

Status of Amendments An amendment was filed on May 14, 2001 to respond to Examiner's objection to claim 17 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Accordingly, applicant amended claim 17 to delete "encompassed".

Summary of Invention The invention is based on the object of providing a sealing medium which develops sufficiently high adhesive strengths when applied in an extremely thin layer, has the consistency of a printing ink which can be processed with conventional printing machines, allows insignificant uptake of active ingredient because of its chemical composition, in particular displays a barrier function towards volatile active ingredients such as nicotine, and can be used without difficulty, for example without elaborate drying of a laminating adhesive or melting of a comparatively thick sealing film, in simple processes (page 2, lines 1-14). The object is achieved by the creation of a packaging system made of composite packaging material for the sealed enclosure of products, such as transdermal therapeutic systems, which are subject to changes due to exchange with their environment or to partial volatilization of active ingredient. This packaging system contains, on the product side, a barrier layer to which a heat sealing layer is applied by providing a heat sealing lacquer which is in the form of a liquid phase for applying extremely thin sealing layers in a printing process, for example to partial areas of composite packaging materials (page 2, lines 18-21). The achievement of the invention is that, as a consequence of its small layer thickness, the sealing lacquer permits insignificant uptake of active ingredient (page 2, lines 23-25). Moreover, the possibility of applying the sealing lacquer of the invention in a printing process only to specific areas of packaging materials (page 2, lines 26-28) means a further reduction in the amount used. Thus the costs of materials as well as possible interactions with active ingredient in the packaged plaster are likewise reduced. The small amount of sealing medium used has advantages both in ecological and in economic respects not only for the production of plaster packaging but also for the disposal thereof. In addition, using a printing process facilitates accurate application of the sealing lacquer to only the sealing area and thus reduces interactions between product and packaging material. On the other hand, use of the sealing lacquer only in the sealing area means that it is possible to have packaging systems in which desired interactions, for example, between product and packaging as in the case of moisture absorbers (page 3, line 6), can take the desired form. By contrast, with the full-area sealing layers previously employed, the films or sheets always formed a first layer completely surrounding the product of a packaging. The invention makes it possible for sealing layers which can be applied thereby to packaging material areas to have weights per unit area

between 1 and 15 g/m², preferably weights per unit area between 2.5 and 3.5 g/m² (page 3, lines 22-25).

Issues The following issues are presented in the appeal:

Issue 1: Was the rejection of claims 9-12 and 14 as being anticipated by Wardwell (U.S. Patent No. 3,938,659) in view of Hunt et al. (U.S. Patent No. 5,077,104) proper?

Issue 2: Was the rejection of claims 13 and 15 being anticipated by Wardwell (U.S. Patent No. 3,938,659) in view of Hunt et al. (U.S. Patent No. 5,077,104) and further in view of Flieger (U.S. Patent No. 5,447,772) proper?

Issue 3: Was the rejection of claims 16 and 17 being anticipated by Wardwell (U.S. Patent No. 3,938,659) in view of Hunt et al. (U.S. Patent No. 5,077,104) and further in view of Wilking (U.S. Patent No. 5,698,217) proper?

Grouping of Claims Claim 9 is the only independent claim; claims 10, 11, 13, 14, and 15 depend from claim 9, claims 12 and 16 depend from claim 10 and claim 17 depends from claim 16. Claims 13 and 15 (Group 2) and claims 16 and 17 (Group 3) are believed to be separately patentable from claims 9-12 and 14, for the reasons set forth in the following argument. Similarly, the claims of Group 2 are believed to be separately patentable from the claims of Group 3, and vice versa,

Argument Applicant believes that the rejections are improper and should be reversed. First of all, applicants wish to emphasize that the heat sealing layer presented in the present claim 9 differ from the references, as explained below, with respect to the following limitations:

a single layer and not a laminate, and
resistant to the pharmaceutically active ingredient, and
not thicker than 15 g/m² weight per unit area, and
applied from a liquid phase in a printing mode, and
displays adhesion forces in the region of strength of the packing material.

Issue 1:

Applicant respectfully traverses the Examiner's rejection of claims 9-12 and 14 as being anticipated by Wardwell (U.S. Patent No. 3,938,659) in view of Hunt et al. (U.S. Patent No. 5,077,104). Wardwell teaches a frangible bonding system utilizing blush lacquer as frangible link and a heat sealable material. Packages comprising this frangible bonding system were particularly adapted for packing pharmaceutical products, which, in column 1, lines 13-15, are

defined as sterile surgeon's gloves, masks, surgical dressings and surgical kits rather than pharmaceutical compositions comprising pharmaceutically active agents. In column 5, lines 57-65, it is stated that the heat seal material shall provide a poor barrier to ethylene oxide which is a gas used for sterilization and that the gas penetrates the heat seal coating. This indicates that the desired heat seal material is permeable to gas and thus would be permeable to volatile active agents also.

Applicant respectfully submits that Examiner is incorrect in his statement in paper #8, page 4, that "Wardwell teaches ... a heat sealing layer wherein the heat sealing layer is formed by an active ingredient-resistant". Instead, Wardwell discloses a blush laquer which may be applied by printing (see column 5, lines 15-17), onto which the adhesive material or heat sealing layer is overlaid forming a bonding system; application of the heat sealing layer is by hot melt or in solution or suspension (see column 5, lines 42-45). Wardwell does not apply his heat sealing layer by printing, nor does he even mention active ingredient-resistance. Thus, taken by itself, Wardwell's teaching clearly leads away from the present invention. Therefore, it is believed that those skilled in the art would consider the teaching of Wardwell as unsuitable to solve the problem underlying applicant's inventive packaging because the heat sealing layer is not applied by printing and, since it enables penetration, is not resistant to the active agents.

On the other hand, Hunt et al. teach a very particular package for packing nicotine. This package essentially comprises a laminate of two different barrier layers. First, it contains a nicotine barrier layer comprising a nitrile rubber modified acrylonitrile-methyl acrylate copolymer and it further contains a nicotine degradation agent barrier layer in the form of an aluminum foil. The heat sealable nitrile rubber modified acrylonitrile-methyl acrylate copolymer is particularly suitable for nicotine. However, it remains unknown whether this polymer is also resistant to other pharmaceutically active agents. The aluminum foil provides a general protection against light and moisture to prevent degradation of the active agent. While it is impermeable to most active agents, aluminum foil is not heat sealable nor does it display adhesive forces in the strength of the packing material. Furthermore, to serve as a barrier layer being impermeable to moisture, gases, flavors and light, aluminum foil has to have a thickness of at least $20\text{ }\mu\text{m}$, see Lexikon Folientechnik, attached. Given its specific weight of 2.702 g/cm^2 , see Römpf Chemie-Lexikon, attached, an aluminum barrier layer would have a weight of at least 54.05 g/m^2 which would be far beyond applicant's heat sealable layer's claimed weight of 15 g/m^2 .

Obviousness rejections are based on 35 U.S.C. 103(a). In ACS Hospital Systems, Inc. v. Montefiore Hospital, 221 USPQ 929, 933 the court stated that "Obviousness cannot be

established by combining the teachings of the prior art to produced the claimed invention, absent some teaching or suggestion supporting the combination." The court elaborated by stating that "Under section 103, teaching of references can be combined *only* if there is some prior suggestion or incentive to do so." *Id.* The Examiner provides no such suggestion or teaching to support this combination of references. Applicant believes that one of ordinary skill in the art would not have been motivated to combine the teachings of Wardwell and Hunt et al. While, as Examiner states, each patent is a pharmaceutical packaging system using heat sealing, one can clearly distinguish between them in that Wardwell's system contains pharmaceutical supplies while Hunt et al's system contains pharmaceutical ingredients. Further, Wardwell's system enables gas penetration while Hunt et al. prevents it.

Moreover, a combination of both teachings might possibly suggest developing a frangible package comprising two different barrier layers, i.e. a laminate. However, a different, much simpler solution is presented by the present invention where a single layer is heat sealable, resistant against active agents and fairly low in weight. Such an unusual sealing layer as specified in the present claim 9 is definitely not suggested by the combination of both aforementioned teachings and those skilled in the art would not have been enabled to reach the present invention. Applicant respectfully requests that this rejection of claims 9-12 and 14 as being anticipated by Wardwell in view of Hunt et al. be withdrawn.

Issue 2:

Applicant respectfully traverses the Examiner's rejection of claims 13 and 15 as being anticipated by Wardwell (U.S. Patent No. 3,938,659) in view of Hunt et al. (U.S. Patent No. 5,077,104) and further in view of Flieger (U.S. Patent No. 5,447,772). Applicant believes there is no difference, whether or not the previous two publications, each one by itself or in combination with each other, are combined with the teaching of Flieger. Flieger presents a resealable bond between two or more overlapping multi-layer film surfaces comprising a plurality of closely spaced, interconnecting indentations, such bond to be used in general with plastic packaging. Any heat sealable compositions could be used, as shown in column 5, line 29 to column 6 line 8, regardless of whether they are resistant to an active ingredient or not. Among the putative polymers suitable, one can also find ethylene-methylacrylic acid copolymers.

Applicant believes that one of ordinary skill in the art would not have been motivated to combine the teachings of Wardwell and Hunt et al. with Flieger. As stated above, applicant finds no motivation to combine the teachings of Wardwell and Hunt et al. Further, Flieger is addressed to plastic packages and has no reference, either direct or indirect, to pharmaceuticals. Moreover, the heat sealing aspect of Flieger is merely the ability of certain compositions to be

sealed directly together with heat as opposed to directly sealing the overall package together with heat. Flieger's invention relates to resealable bonds which are not heat sealed. Applicant respectfully submits that those skilled in the art would not have been enabled, with these teachings, to reach the present invention. Accordingly, applicant respectfully requests that this rejection of claims 13 and 15 as being anticipated by Wardwell in view of Hunt et al. and further in view of Flieger be withdrawn.

Issue 3:

Applicant respectfully traverses the Examiner's rejection of claims 16 and 17 as being anticipated by Wardwell (U.S. Patent No. 3,938,659) in view of Hunt et al. (U.S. Patent No. 5,077,104) and further in view of Wilking (U.S. Patent No. 5,698,217). Applicant again respectfully believes that, as discussed above, there is no motivation to combine Wardwell with Hunt et al. Moreover, the Examiner states in paper #8, page 7, that "... Wardwell does not teach a packaging system comprising a layer within an area which is enclosed by the sealing layer, said enclosed layer entering into interaction with the packaged product and wherein the enclosed layer is formed by a moisture absorbent layer." In fact, Wardwell, in column 5, lines 67-68 and column 6, lines 1-2, suggests the use of heat seal materials which cannot be attacked by high temperature steam, that is, heat seal materials that, while permeable, do not absorb moisture. Wilking, by contrast, teaches a desiccant package for transdermal therapeutical systems with a special desiccant compartment, which is separated from the compartment containing the transdermal therapeutic system. The desiccant package is adhered to the water vapor impermeable sheet of the desiccant compartment by means of a pressure sensitive adhesive which immobilizes the package within the product package. The desiccant package is configured in any way that defines a compartment, see column 3, lines 45-46, yet this package does not touch or interact with the transdermal therapeutical system or its active substance, see Fig. 1. In claim 17 of the present application, a solution is presented where a "simple" desiccant layer interacts with, that is, directly touches, the packaged product. Thus the desiccant device is one layer instead of the package of Wilking. Moreover, Wilking's product resides in a product receiving space and does not abut the desiccant package. These distinctions results in applicant's packaging system being easier and more cost effective to manufacture.

Applicant believes that the teaching of the desiccant package according to Wilking does not suggests the use of a desiccant layer, especially not a desiccant layer which interacts with the packaged product. Applicant further believes that one of ordinary skill in the art would not have been motivated to combine the teachings of Wardwell and Hunt et al. with Wilking, since the commonality between both references is merely that each is a packaging system using heat

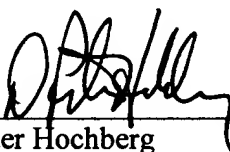
sealing for distinct types of pharmaceuticals. Wilking is packaging active substances while Wardwell is packaging surgical gloves and masks; Wilking is concerned with removing moisture from his package while Wardwell introduces moisture as part of the sterilization process. Applicant respectfully requests that this rejection of claims 16 and 17 as being anticipated by Wardwell in view of Hunt et al. and further in view of Wilking be withdrawn.

Applicant acknowledges the failure to respond to the Examiner's statements concerning the arrangement of the specification in paper #8, page 2, paragraph 1, but applicant will make the corrections to add section headings under separate cover.

The Examiner objected to claim 17 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Accordingly, applicant amended claim 17 to delete "encompassed" in an Amendment filed May 14, 2001.

For the foregoing reasons, it is respectfully requested that the rejection of claims 9-17 under 35 U.S.C. § 103 be reversed.

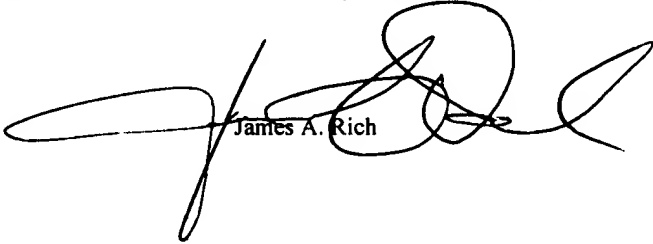
Respectfully submitted,

By: 
D. Peter Hochberg
Reg. No. 24,603

DPH/KRV
Enc.: Appendix A; Appendix B
D. PETER HOCHBERG CO., L.P.A.
1940 East 6th Street, 6th Floor
Cleveland, Ohio 44114
(216) 771-3800

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. 1.8(a))

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April 16, 2002
Date

James A. Rich

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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APPENDIX A
Claims as Currently Presented

Claims:

9. Packaging system made of composite packaging material for the sealed enclosure of products being subject to changes due to exchange with their environment or to partial volatilization of active ingredient comprising a barrier layer on the product side, to which barrier layer there is applied a heat sealing layer wherein the heat sealing layer is formed by an active ingredient-resistant layer having a layer thickness of maximally 15 g/m^2 weight per unit area, said active-ingredient resistant layer being applied from the liquid phase in a printing method and, after heat-activated sealing, displaying adhesion forces which are in the region of strength of the packaging materials.
10. The packaging system of claim 9 wherein the heat sealing layer covers only the sealing area.
11. The packaging system of claim 9 wherein a layer thickness of the heat sealing layer is between 2.5 and 3.5 g/m^2 weight per unit area.
12. The packaging system of claim 10 wherein a layer thickness of the heat sealing layer is between 2.5 and 3.5 g/m^2 weight per unit area.
13. The packaging system of claim 9 wherein the heat sealing layer comprises an ethylene/methacrylic acid copolymer dispersion which displays no measurable active ingredient uptake.
14. The packaging system of claim 9 wherein the barrier layer comprises aluminum.
15. The packaging system of claim 9 wherein the chemical composition of the heat sealing layer is inert to nicotine.
16. The packaging system of claim 10 comprising a layer within a surface encompassed by the sealing area, said layer being able to enter into interaction with the packaged product.
17. The packaging system of claim 16 wherein the encompassed layer is formed by a moisture absorbent layer.



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APPENDIX B

Claim 17 as in Proposed Amendment

17. The packaging system of claim 16 wherein the [encompassed] layer is formed by a moisture absorbent layer.